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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/049,427 | 05/06/2002 | Karl Bruce Thor | X-11072 | 1087 |

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EXAMINER

TRAVERS, RUSSELL S

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/15/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|---|-----------------------------|
| Application No. 10/049,427 | Applicant(s) Thor |
| Examiner R.S. Travers J.D., Ph.D. | Art Unit 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 19-29, 31, 32, and 34-55 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 19-29, 31, 32, and 34-55 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

Art Unit:

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 19-23, drawn to an article of manufacture employed to treat premature ejaculation containing various selective serotonin re-uptake inhibitors (SSRI)
- II. Claims 24-25, 31-32, 34-35, 43-50 and 55, drawn to treating various sexual dysfunction maladies by administering various therapeutic compositions containing various SSRI compounds.
- III. Claims 26-28, 36-42 and 51-54, drawn to treating premature ejaculation and related maladies by administering various therapeutic compositions containing various SSRI compounds.

The presented inventions are only linked by the presented specification; with each invention requiring a separate distinct search and consideration. The instant application was filed under 35 USC 371, requiring restriction by unity of invention. The authority for this restriction practice is found in 37 CFR 1.499. To restrict a case filed under 35 USC 371, the Examiner need not consider the burden posed by examining additional inventions; although such burden is present in the instant case.

Patent Cooperation Rules (PCT) Rules 13.1 and 13.2 permit in a single application only one invention. Thus, an application presenting more than one invention, as in the instant case, is appropriately restricted for lack of unity.

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The above delineated inventions differ as various methods of manufacture for compositions and patentably distinct methods of therapy; are independent and patentably distinct each from the other. The grouped inventions differ as to their physical form and intended use, a reference which would anticipate the invention of one group would neither anticipate, nor make obvious the inventions in the other groups. The searches are not co-inclusive as indicated by the diverse nature of the subject matter. One skilled in the art would readily practice the invention of one of the above groups with out infringing and or practicing the invention of another group. The subject matter is unique and has acquired a separate status in the art and is fully capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

The grouped inventions are patentably distinct, a reference which would anticipate, or make obvious, any invention from groups I-III would not necessarily obviate, or anticipate, the inventions in any other group. The searches are not co-inclusive as indicated by the diverse nature of the subject matter, thus, would represent an undue burden on Examiner. One skilled in the art would readily practice the invention of one of the above groups with out infringing and or practicing the invention of another group. Sexual dysfunction, as set forth in Group II, encompasses a plethora of maladies, to include such species as erectile dysfunction. Premature ejaculation, not seen as related to maladies such as erectile dysfunction by the skilled artisan, would

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therefore be patently distinct from the maladies recited in the claims of Group III. Thus, the subject matter is unique and has acquired a separate status in the art and is fully capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variations or clearly admit on the record that this is the case. In either instance, if Examiner finds one of the inventions unpatentable over the prior art, the evidence may be used in a rejection under 35 USC 103 of the other invention.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



**Russell Travers
Primary Examiner
Art Unit 1617**